From: Cheryl Howe

To: Ben Baker; David (DW) Gustafson; Denise Kay

Date: Fri, Nov 18, 2005 6:41 PM

Subject: Technical Review Comments on Dow/Entrix Screening Level and Baseline Ecological

Risk Assessments

Attached are the technical review comments on the Dow/Entrix Screening Level Ecological Risk Assessment and Baseline Ecological Risk Assessment (BERA) submittals, as received from the Department of Environmental Quality's (DEQ) contractor, Galbraith Environmental Sciences, LLC (GES), and the U.S. Environmental Protection Agency (U.S. EPA). There appear to be some conversion artifacts in the U.S. EPA SLERA comment document. However, I am forwarding it in the interest of getting it to you this week. If necessary, I can provide a better version of this document next week.

Some discussion may be needed to clarify how the U.S. EPA comments mesh with the GES comments and the DEQ's requirements for conducting the ecological risk assessment. The DEQ reserves its rights to provide further comments and/or clarifications following review of these comments by Dow/Entrix and any necessary meetings.

If I have missed anyone who should have received this, please forward it on to them. Thank you.

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MEMORANDUM

To: Allan Brouillet, Brenda Brouillet, Sue Kaelber-Matlock

FROM: Hector Galbraith, Galbraith Environmental Sciences, LLC

DATE: September 29, 2005

SUBJECT: Review of ENTRIX Screening Level Risk Assessment Work Plan

1.0 INTRODUCTION

At your request, I have reviewed the ENTRIX document – *Draft Screening-Level Ecological Risk Assessment Work Plan for the Tittabawassee River and Associated Floodplains* issued in July 2005 (hereafter referred to as ENTRIX, 2005). In addition, a verbal discussion with ENTRIX and DOW personnel on September 16, 2005 resulted in important supplementary information regarding the proposed screening-level assessment being provided. This memorandum details the results of my review of the ENTRIX (2005) work plan together with the September 16 additional information .

Before presenting the results of my review, and in order to place this document in its larger context, there are two important factors that should be recognized regarding the scope and purpose of the ENTRIX (2005) document:

- 1. The document reviewed is a <u>work plan</u> that describes proposed approaches to evaluating risks. It does not contain the results of actual risk analyses.
- 2. The risk assessment approaches described in the work plan are screening-level. That is, they do not address questions about the magnitude, distribution and/or prevalence of risks, but focus on one question only: can we safely disregard the possibility of risks to ecological receptors at the site? In ENTRIX (2005), the screening-level approach is intended primarily to identify contaminants for which we can safely disregard the possibility of ecological risk and, conversely, to identify those that fail this initial test and that need to be examined in greater detail in the next stage of the risk assessment process (the baseline Ecological Risk Assessment [BERA] phase).

MDEQ has already developed a screening-level ecological risk assessment (SLERA) for the Tittabawassee River's terrestrial floodplain ecosystem and it concluded that PCDD/PCDFs cannot be discounted as sources of unacceptable risk to ecological receptors. However, the MDEQ SLERA did not evaluate risk from other contaminants that could have been released into the Tittabawassee River.

In conducting this review, I have focused on four specific questions:		
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- Is the proposed overall approach adequate and consistent with that required to perform valid screening-level risk analyses?
- Are the proposed specific technical approaches appropriate and valid for this preliminary level of risk analysis?
- Does the proposed work recognize previous data gathering efforts and analyses and how necessary are the proposed analyses, given the risk assessment activities previously performed at the site?
- What are the implications of the proposed studies for the future of the MDEQ dialogue/negotiations with the Dow Chemical Company?

To address these issues I have organized my comments into two sections. The first deals with general or overarching issues (Section 2). These are concerns, areas of uncertainty, or questions that I have about the overall scope, direction, and comprehensiveness of the general approach and activities described in the Screening-Level Ecological Risk Assessment (SLERA) work plan (ENTRIX, 2005). Section 3 details specific issues that I have identified as needing to be addressed before the work plan can be considered adequate. In Section 4 of this memorandum I summarize the results of my review in the context of the seven questions raised above and discuss their implications for future evaluation of risks at this site.

2.0 GENERAL ISSUES

The overall approach used by ENTRIX in the work plan is adequate and appropriate for screening-level assessments. It conforms broadly to the procedure developed by U.S. EPA (EPA, 1998) and which has become generally accepted by the risk assessment community. ENTRIX correctly recognizes the screening purposes of the approach and its limitations. Nevertheless, I identified a number of general or overarching issues that require clarification before the work plan can be considered entirely adequate

The need, or otherwise, for further risk assessment activities and the failure to recognize previous activities. Two ecological risk assessments have already been performed for the Tittabawassee River and its floodplain. In GES (2003) risks posed by PCDDs and PCDFs in the aquatic environment and its associated food chains were evaluated. In GES (2004) the same was done for the terrestrial floodplain environment. Since it included a relatively large amount of site-specific data (sediments, fish, bird eggs), the former ecological risk assessment can be considered as being closer to the definitive end of the risk assessment scale (as distinct from the screening-level end). The terrestrial ecological risk assessment performed by MDEQ should be considered screening-level.

While there is clearly a need for a more definitive analysis of risks on the floodplain, and there is likewise a need for the assessment of aquatic risks posed by contaminants other than PCDDs and

PCDFs, the perceived need for further aquatic risk estimates for PCDDs and PCDFs in the Tittabawassee River is doubtful. Furthermore, as discussed below, sediment sampling in the Saginaw River and Saginaw Bay has clearly indicated that ecological risk may be "exported" out of the Tittabawassee River and into downriver areas. As yet, these downriver risks have not been adequately examined. I regard this as a more appropriate focus for future aquatic risk assessment activities, rather than a re-examination of the Tittabawassee River aquatic system.

Geographic scope of the proposed analysis. At several places in the document (including the map in Figure 2-1, p.2-3) the geographical area of investigation is defined as the reach of the Tittabawassee River and its floodplain from Midland downriver to the confluence with the Saginaw River. Discussions with Dow and ENTRIX personnel on September 16, 2005 confirmed that no risk assessment activities are planned for downriver of the confluence. The September 16 discussions also confirmed that the reason for this geographical truncation is regulatory, rather than scientific: Dow and ENTRIX maintain that, under the terms of the permit with the State, the reaches further downriver do not need to be addressed in the current round of risk assessment activities.

Regardless of the regulatory issues, sediment sampling by the Army Corp of Engineers in 1998 and 1999 detected TCDD-EQ concentrations of up to 610 ppt (WHO avian TEFs) in the inner Saginaw Bay and exceeding 2,000 ppt in Saginaw River. More recent sampling in the Saginaw River by MDEQ and by Dow identified TCDD-EQ concentrations that were greatly elevated above background (approaching 50,000 ppt – WHO avian TEFs). The congeners that make the greatest contributions to this toxicity are the same as those in the Tittabawassee River, indicating the likelihood of a common source. Furthermore, preliminary evaluations performed by MDEQ (GES, 2003) on the Army Corp of Engineers data set indicate that the possibility that these concentrations pose unacceptable risks to ecological receptors cannot be disregarded.

Ignoring the permit and regulatory issues and concentrating solely on the implications of the risk assessment, it is obvious that the ecological risk assessment activities proposed in the ENTRIX work plan will not capture or address all of the potential <u>watershed</u> ecological risks due to PCDDs and PCDFs originating in Midland. Specifically, risks posed by these contaminants transported downriver of the confluence of the Tittabawassee and Saginaw Rivers will not be included.

The omission of PCDDs and PCDFs from the screening-level assessment. ENTRIX (2005) proposes that PCDDs and PCDFs not be included in the screening-level assessment. Before discussing this issue further, I acknowledge that I agree with ENTRIX that the results of a SLERA should not be regarded as rigorously predictive of risk, and its primary purpose is to identify and eliminate from further analyses contaminants that can be safely regarded as not likely to pose unacceptable risks. Nevertheless, the relative magnitudes of SLERA hazard indices can provide at least an order of magnitude comparative assessment of the *potential* contributions to risk by each of the contaminants. Thus, a SLERA, in addition to eliminating contaminants from unnecessary analysis, may also provide a useful early indication of the relative importances of each of the contaminants that fail the "SLERA test".

The reasons for the omission of PCDDs/PCDFs from the proposed ENTRIX SLERA are not stated fully in the SLERA work plan, but only vaguely described as (for example) "based on historical data, it is *assumed* thatPCDDs and....PCDFs will continue to be COPECs" (my italics). In verbal discussions with Dow and ENTRIX personnel on September 16, they clarified their position by explaining that the reason that PCDDs and PCDFs are not to be included in the SLERA is because they accept the results of the State's previous efforts to evaluate risks posed by these contaminants in the Tittabawassee River and its floodplain. Dow and ENTRIX apparently believe that since the State has already concluded that PCDD/PCDFs pose unacceptable risks to biota, they need not be included in their proposed screening-level assessment. If my interpretation of what was communicated is correct, and if Dow and ENTRIX accept the State's conclusions, it should be clearly stated in the ENTRIX (2005) work plan. Otherwise, I would recommend (for the reasons given at the beginning of this paragraph) that PCDDs and PCDFs should be included in the screening-level evaluation.

Screening-level risk assessment – worst case? In their Introduction to the SLERA work plan (p. 1-1), ENTRIX (2005) describe the necessary degrees of protectiveness that have to be incorporated into screening level assessment to minimize the likelihood of false negative conclusions. They then go on to characterize the results of screening-level assessments as "worse case". The implication of this is that it confers a level of "over-protection" on receptors. This is not necessarily the case: just because protective parameters have been used, it does not necessarily follow that all potential ecological receptors are over-protected. While SLERA risk estimates probably define the upper end of the risk spectrum at a site, and may be adequately protective for most situations and biota, they may not be protective enough for some eventualities, for example sensitive or highly sensitive organisms with small home ranges that are superimposed on areas of maximum contamination. Also, it is a fact that we do not know how sensitive or insensitive the vast majority of species that occur in the assessment area are to PCDDs and PCDFs, and while we may hypothesize that we are being adequately protective in our selection of parameters we cannot be entirely sure.

Selection of ecological receptors and exposure pathways. It is not clear from the Entrix (2005) document how ecological receptors will be selected or which species have been selected. This should be clarified so that MDEQ can more fully evaluate the adequacy of the proposed work. Also, during verbal conversations on September 16 it was stated that hooded merganser eggs had been collected and that the results of their analyses would be included in the risk assessment. This should be made explicit in the SLERA work plan.

Uncertainties and the uncertainty analysis. Section 4-2 (p. 4-3) of the workplan correctly points out the need for an uncertainty analysis at the conclusion of the screening evaluation. It should be acknowledged that this uncertainty analysis should include all areas of uncertainty, including those that may result in the underestimation of risk. An example of the latter would be the fact that our knowledge is very incomplete regarding how sensitive or insensitive to PCDDs and PCDFs most species that occur in the assessment area actually are.

3.0 SPECIFIC COMMENTS

Section 2.2, Figure 2-3. p.2-4. What do the error bars represent (range, standard error, standard deviation)?

Section 2.4.1, p.2-5. penultimate sentence in final para. The existing data set includes more than "a few native whole fish samples". This creates the mistaken impression that relatively little is known about contamination in fish in the study area. In 2002 MDNR and MDEQ collected and analyzed more than 80 individual fish from 4 resident species. Also, subsequent to that in 2004, MSU collected samples from "forage fish" and two additional species (northern pike and bowfin) from the Tittabawassee River downriver of Midland. TCDD-EQ in the tissues of these samples (including the forage fish) approximated those high levels found in the MDEQ/MDNR samples. Thus, to create the impression that little is known about contaminants in fish from the study area is disingenuous. It would be more accurate to conclude that existing data confirm that elevated concentrations of TCDD-EQ are widespread throughout the fish community.

Section 2.4.1, p.2-6. Table 2-1. MDEQ's 2001 sediment sampling is missing from this table. Also the bird egg data is jointly MDEQ and USFWS.

Section 2.4.2, p.2-7. What is meant by the statement that "no comprehensive ecological evaluations...study area"? Is it intended that the SLERA will be such an evaluation?

Section 3.1.1.1, p.3-1. The ecological receptors ("key receptors") that are to be the focus of the SLERA are not identified in the ENTRIX work plan. They should be identified, together with the rationales for their selection.

Section 3.1.1.1, p.3-2 first para. The statement about the postulated "very limited assimilation and accumulation of particulate-bound of COPECs intosmall mammals" needs to be clarified. Is this a statement about conditions at the site, or is it intended to be more general? Either way it needs to be supported by references and/or data.

Section 3.1.1.2, p.3-2. 2nd sentence. Should Equation 5-1 be 3-1?

Section 3.1.1.2, p.3-2. Are the "site use factor" and the "area use factor" synonymous?

Section 3.1.1.2, p.3-2. How will the "fractional absorption value" be determined? Will it be site-specific or based on the literature?

Section 3.2.2, p.3-4. Uncertainty factors. Uncertainty in important variables in risk assessment analysis can result in the underestimation of risk, as well as its overestimation. Both tendencies should be addressed and evaluated in any adequate uncertainty analysis. For example, it is not clear from the SLERA work plan how the high degree of uncertainty regarding our lack of knowledge about the sensitivity, or otherwise, of the majority of bird and mammal species at the site be addressed?

Section 2.5, p.2-7 Typo. Black-crowned night heron should be black-crowned night-heron.

Section 4.1, p. 4-1 Typo. There are no Equations 2-1 or 2-2 in the text. Should it read 4-1 and 4-2?

Section 1.4, p.1-2, The Section 3.0 description is incomplete.

Section 6.0, p.6-1 Typo in Galbraith.....

Section 6.0, p.6-2 Reference to University of California is incomplete.

4.0 SUMMARY AND IMPLICATIONS FOR FUTURE EVALUATION OF RISKS

In terms of specific proposed processes and methods, the ENTRIX (2005) work plan describes a screening-level assessment that largely conforms to the approaches that are currently "best practices" within the ecological risk assessment field. Nevertheless, a number of technical uncertainties and areas of potential dispute were identified and these are listed above. However, my main concerns with the SLERA work plan are primarily focused on three overarching issues that set the scope, direction, and context of the ERA process, rather than technical specifics.

First, while the stipulations of the MDEQ-Dow permit might require an aquatic Baseline Ecological Risk Assessment, I am not convinced that it is scientifically necessary (within the Tittabawassee River), given that the State has already performed a definitive level analysis and found widespread unacceptable risk from PCDD/PCDF contamination. Further risk assessment activities may be more profitably focused on four issues that are currently less well understood: risks posed by contaminants in the Tittabawassee River other than PCDD/PCDFs; risks posed by contaminants downriver of the Tittabawassee River; extending the MDEQ screening level risk assessment for the Tittabawassee River floodplain to a more definitive level of analysis; and, lastly, evaluating the risk implications of potential remediation goals and methods.

Second, the aquatic and terrestrial environments downriver of the confluence of the Saginaw and Tittabawassee Rivers are omitted from the proposed risk assessment activities despite convincing evidence that these areas are highly contaminated with the same PCDDs and PCDFs that are prevalent upriver to Midland. I cannot comment on limitations on ERA activities imposed by the existing MDEQ-Dow permits. However, it should be realized that if the downriver sections are not addressed, the risks due to Dow PCDDs and PCDFs within the watershed may not be fully described.

Last, the omission of PCDDs and PCDFs from the screening-level analyses. The reason given for this by Dow and ENTRIX in verbal communication is that they "are building on the State's work". If this means that the risk estimates that the State has already developed have been accepted by Dow and its consultant it should be clearly stated as such in the SLERA work plan. If this not the case, PCDDs and PCDFs should be included in the ENTRIX SLERA for the sake of clarity of process and to allow the comparison of the approximate relative importances of each of the contaminants.

5.0 REFERENCES

ENTRIX. 2005. Draft Screening-Level Ecological Risk Assessment Work Plan for the Tittabawassee River and Associated Floodplains. Entrix, Inc. East Lansing, Michigan. Prepared for Dow Chemical Company.

GES. 2003. Tittabawassee River Aquatic Ecological Risk Assessment. Prepared by Galbraith Environmental Sciences, Newfane, VT., for MDEQ, Bay City, MI.

GES. 2004. Tittabawassee River Floodplain Screening-level Ecological Risk Assessment. Prepared by Galbraith Environmental Sciences, Newfane, VT., for MDEQ, Bay City, MI.

U.S. EPA. 1998. Guidelines for Ecological Risk Assessment. EPA/630/R-95/002F.

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MEMORANDUM

To: Allan Brouillet, Brenda Brouillet, Sue Kaelber-Matlock

FROM: Hector Galbraith, Galbraith Environmental Sciences, LLC

DATE: September 29, 2005

SUBJECT: Review of ENTRIX Baseline Ecological Risk Assessment Work Plan

1.0 INTRODUCTION

At your request, I have reviewed the ENTRIX document – *Draft Baseline Ecological Risk Assessment Work Plan for Polychlorinated Dibenzo-p-dioxins (PCDDs) and Dibenzofurans (PCDFs) in the Tittabawassee River and Associated Floodplains* released in July 2005 (hereafter referred to as ENTRIX, 2005a). In addition to the risk assessment work plan, my review also extended to its various attachments. These included the Quality Assurance Project Plan (Appendix A), the Baseline ERA Study Plans (Appendices C through G), and the Standard Operating Procedures (Appendix H). In addition to the written materials, a verbal discussion took place with ENTRIX and DOW personnel on September 16, 2005 regarding their risk assessment proposals. This resulted in important supplementary information regarding the proposed Baseline Ecological Risk Assessment (BERA) being provided. This memorandum details the results of my review of the ENTRIX (2005a) work plan and its attachments, together with the September 16 additional information.

In conducting the review, I have focused on four specific questions:

- Is the proposed overall approach adequate and consistent with that required to perform valid baseline ecological risk assessment analyses?
- Are the proposed specific technical approaches used consistent with the state of the science?
- Will the proposed approaches adequately capture the magnitude and spatial distribution of risks to ecological receptors throughout the area of contamination?
- What will be the contribution of the proposed analyses, given the data collection and risk assessment activities previously performed at the site?

To address these issues I have organized my comments into two sections. The first deals with general or overarching issues (Section 2). These are concerns or areas of uncertainty I have identified regarding the overall scope, direction, and comprehensiveness of the general approach and activities described in the Baseline Ecological Risk Assessment (BERA) work plan. Section 3 details specific issues that I have identified as needing to be addressed before the work plan can be considered adequate.

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2.0 GENERAL ISSUES

I have identified seven overarching issues that should be recognized by MDEQ in their consideration of the ENTRIX BERA work plan:

1. The relationship of the BERA to previous studies and data collection and analyses, and the need for further ecological risk assessment. Since about 1980, a large quantity of data has been gathered characterizing the degree and extent of environmental contamination in the Tittabawassee River watershed. These data sets describe contaminant concentrations in sediments, surface water, soils, and biota. Based on these data, two ecological risk assessments have already been performed for the Tittabawassee River watershed (GES, 2003; GES 2004). The former focused on the aquatic environment, while the latter addressed risks to biota on the floodplain of the Tittabawassee River. Since it included a relatively large amount of site-specific data (sediments, fish, bird eggs), the former ecological risk assessment can be considered as being closer to the definitive end of the risk assessment scale (as distinct from the screening-level end). The floodplain (terrestrial) ecological risk assessment performed by MDEQ should be considered screening-level.

Reading the ENTRIX (2005a) work plan, one could be forgiven for concluding that comparatively little information was available regarding contamination of the study area by organochlorines, bioaccumulation in food chains, or exposure and risks to predatory wildlife. This is because the ENTRIX work plan fails to acknowledge, to an adequate extent, the fact that a large amount of data has already been gathered and analyzed. In fact, the Tittabawassee Watershed is a comparatively well-characterized system. It is also the case that contaminant concentrations in many of the components of the aquatic and terrestrial ecosystems have been assessed and in each the result is the same – high levels of contamination that greatly exceed baseline. During the September 16 discussions, ENTRIX personnel stated that their proposed work should be regarded as "building on" or "extending" previous studies (including MDEQ studies). If this is the case, a more comprehensive acknowledgement of previous studies and their contributions to our understanding of environmental risks should form part of the BERA work plan.

The previous studies notwithstanding, there are three outstanding risk assessment "data needs" for the Tittabawassee River watershed:

- 1. There is a need for a more definitive analysis of risks on the floodplain (where the MDEQ assessment is at the screening level).
- 2. There is a need for the assessment of aquatic risks posed by contaminants other than PCDDs and PCDFs in the aquatic environment.
- 3. Sediment sampling in the Saginaw River and Saginaw Bay (discussed below) has clearly indicated that ecological risk may be "exported" out of the Tittabawassee River and into

downriver areas. As yet, however, these downriver risks have not been adequately examined. They could be a much-needed focus of future risk assessment.

The studies described in the ENTRIX BERA clearly focus on data need numbers 1 and 2. They do not, however, address data need number 3 (see below). Moreover, a large component of the BERA work plan describes studies that revisit an issue that the State has already completed much work on: the risks to ecological receptors in aquatic food chains in the Tittabawassee River from PCDD/PCDFs. Future time and resources would be better spent if the BERA focused mainly on the three data needs identified above.

2. Geographic scope of the proposed analyses. At several places in the document (e.g., p. 1-1 first para., p. 1-4 first para., Appendix C, Figure C-1) the main geographical area of investigation ("the Site") is defined as the reach of the Tittabawassee River and its floodplain from Midland downriver to the confluence with the Saginaw River. A work plan for a screening-level risk analysis that I previously reviewed (ENTRIX 2005b) also restricted the study area to the Tittabawassee River and its floodplains. This definition of the area of investigation is, however, not entirely consistent: in the package of BERA materials that I received from MDEQ there were three alternative versions of Appendix C, one of which includes plans for sampling on the Saginaw River close to Saginaw Bay. During discussions with ENTRIX personnel on September 16, it was made clear that the BERA will only cover the Tittabawassee River as far downriver as its confluence with the Saginaw River and that Saginaw River and Bay would not be included. During the September 16 discussions ENTRIX and Dow stated that under the terms of the permit with the State the reaches further downriver need not be addressed.

Sediment sampling by the Army Corp of Engineers in 1998 and 1999 detected TCDD-EQ concentrations of up to 610 ppt (WHO avian TEFs) in the inner Saginaw Bay and exceeding 2,000 ppt in Saginaw River. More recent sampling in the Saginaw River by MDEQ and by Dow identified TCDD-EQ concentrations that were greatly elevated above background (approaching 50,000 ppt – WHO avian TEFs. This last maximum concentration is almost an order of magnitude greater than the sediment samples gathered in the Tittabawassee River. The congeners that make the greatest contributions to this toxicity are the same as those in the Tittabawassee River, indicating the likelihood of a common source in Midland. Furthermore, preliminary evaluations performed by MDEQ (2003) on the Army Corp of Engineers data indicate that the possibility that these concentrations pose unacceptable risks to ecological receptors cannot be disregarded.

Ignoring the permit and regulatory issues and concentrating solely on the implications of the risk assessment, it is clear that the ecological risk assessment activities proposed in the ENTRIX BERA work plan will not capture or address all of the potential <u>watershed</u> ecological risks due to PCDDs and PCDFs originating in Midland. Specifically, risks posed by these contaminants transported downriver of the confluence of the Tittabawassee and Saginaw Rivers will not be included.

3. Multiple lines-of-evidence approach. Throughout the BERA work plan (ENTRIX, 2005a) it
is repeatedly stated that the intended approach to assessing risks to wildlife will be via multiple
lines-of-evidence. In effect, this will mean that estimated and measured exposures, and the

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resulting calculated risks, to wildlife species will not be the only factors used in assessing risk to biota. Using data that is expected to be provided by the Dow-funded Michigan State University Studies, ENTRIX will also incorporate (for example) population abundance, reproductive success, and individual health data into its overall evaluation of risk.

The intent in using a lines-of-evidence approach, particularly one involving measures of population "health", in risk assessment, is typically to address the question "are impacts really occurring among receptors for which risk may or may not be predicted"? Thus, the BERA, as proposed, combines two separate concepts – risk and impact. The reason for utilizing such an approach in risk assessment is often given as being intended to reduce the uncertainty inherent in risk modeling. While uncertainty does exist in the estimation of risk from exposures (modeled or measured), the important question is: to what extent are the results of field studies free from uncertainty? In a multiple lines-of-evidence approach to risk assessment there is often a temptation to regard the results of field studies as free from uncertainty and, therefore, the ultimate arbiters of whether or not risk actually exists. This may not be appropriate since it fails to recognize that the results of field studies may be as fraught with uncertainty as risk assessment modeling and, by disregarding the results of the latter in favor of the former, we may only be replacing one set of uncertainties with another. In effect: field studies may not be "silver bullets" that pierce through uncertainty to provide unambiguous or clear results.

The uncertainties inherent in the interpretation of the results of field studies largely grow out of the uncontrolled or only partially controlled nature of such studies. For example, spatial or temporal differences in the breeding productivity of a wildlife species may arise from factors not controlled for (and potentially uncontrollable) in the study design. Such factors may include: the intermittent presence of a predator in the study area, local weather variability, localized disturbance by humans, or local short-term disruption in the food supply. All of these factors may be likely to go unrecognized by researchers. Nevertheless, it is typical that such factors result in a considerable amount of "noise" in field study results. Against this background of noise, it can be very difficult to unambiguously distinguish the "signal" being sought after. Thus the interpretation of productivity data from the field may be as fraught with as much uncertainty as that of model results.

If the variable being measured in the field is density or abundance a whole new set of uncertainties is introduced. It is well known among population biologists that the densities of organisms measured at specific sites in the field may have little or no relationship to the local presence or lack of stressors. So called "sink populations" of organisms may exist in an area where their population "health" and productivity is low, but they are supported and maintained by immigration from "source" areas where productivity is high.

The concerns that I have outlined above are not intended to imply that field studies do not have a role in ecological risk assessment. They do. However, the results of field studies should not be viewed as unambiguous data that "trump" the predictions of ecological risk prediction. I maintain that, while they may provide useful supporting information, they should be treated as circumspectly as the modeled predictions. If a situation arises where risk modeling predicts unacceptable risk, but field studies fail to show an impact, it should not be regarded as axiomatic that there is no risk, only that the field impacts may not have been detected. This is especially the

case with PCDDs and PCDFs which do not usually result in "kills" in wildlife species, but are expressed in much more subtle and difficult to detect effects, including reductions in fecundity, and morphological and behavioral abnormalities.

In the September 16 discussion, ENTRIX personnel agreed that the field study results would not be used to trump risk assessment predictions but that each line of evidence would be weighted and a final evaluation derived from the integration of these weighted results. This raises the question: how will the various elements be weighted? This should be addressed in the BERA.

- **4. Protection of all receptors.** Presumably, the intent of the BERA is to provide results that will be protective of all, or at least the great majority, of receptors at the site. However, the BERA focuses on only a small subset of receptors. How will the risk assessors ensure adequate levels of protection for all exposed species? For the great majority of birds and mammals that inhabit the assessment area we have little or no information regarding their potential sensitivity or insensitivity to PCDDs or PCDFs. There is no *a priori* reason to assume that some of these species could not be as, or more, sensitive than the most sensitive species that have thus far been tested. It is not clear how the ENTRIX study will extrapolate from the selected receptor species to the ecological community as a whole.
- **5. Receptor species.** The ENTRIX BERA identifies 7 bird species (house wren, tree swallow, great horned owl, belted kingfisher, American robin, bald eagle, and great blue heron) and 3 mammals (mink, meadow vole, and short-tailed shrew) as receptors for the proposed ERA. Several questions are prompted by this list:
 - Why are two species of insectivorous passerine birds being studied? It would seem that one should be sufficient.
 - Why are some highly exposed organisms that MSU is already collecting data for (hooded merganser and wood duck) not included in this list?
 - Why are mammalian top predators on the floodplain absent from the list? Assuming that mink is at least partly aquatic in its diet, there should be animals such as red fox included?
 - Why are no vermivorous animals (e.g., American woodcock) included in the list of receptors?

The impression is conveyed by the BERA list that the only organisms chosen are ones that are already being studied as part of the MSU research. While these animals are, for the most part, suitable candidates, appropriateness, rather than overlap with MSU target organisms, should be the major criterion.

6.	Assessment and measurement endpoints. In Section 3.4 of the BERA work plan
"R	eproductive Success and Population Sustainability" is identified as the overall assessment

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endpoint. To actually put this into use, quantifiable measurement endpoints (e.g., Toxicity Reference Values) must be developed. In Section 5.2 of the BERA work plan there is some discussion about how measurement endpoints may be developed. However, it is still unclear how these will relate back to the assessment endpoints. Can it be assumed that if (for example) the endpoint is avian reproductive success and population sustainability, and that the egg tissue residue threshold (the TRV) is exceeded, resulting in a hazard index of greater than unity, that the standard of the assessment endpoint has not been met?

Also, PCDD/PCDF toxicosis may result in a suite of effects that are not immediately translatable into population effects. For example, edema in embryos, limb malformations. Will these be looked for and will it be assumed that if they are found in study animals they will automatically result in embryo mortality?

7. Use of existing data sets. Several important data sets already are available to describe contamination at the site. These include data sets for sediments, soils, water, and biota. It is not clear from the BERA work plan, however, which, if any, of these data sets will be incorporated into the proposed analyses. The work plan needs a clear statement about which of these data sets are *likely* to be used.

3.0 SPECIFIC COMMENTS

- **p. 1-1, 2nd para.** The statement that there is currently minimal information on PCDD and PCDF levels in the tissues or diets of wildlife is not correct (see general comment 1 above).
- **p. 1-1.** In the Purposes and Scope Section there are 8 bullets describing the purposes of the proposed analyses. Nowhere in these bullets does it explicitly state that the one of these purposes is to identify and quantify <u>risk</u>.
- **p. 1-2, second bullet.** What is meant be pathway analysis and how is it intended to be used to mitigate exposure?
- **p. 3-1, third para.** Use of the term "potential risk". Since some level of risk is always present, potential risk is a misleading term. The real question is whether the risk is acceptable or unacceptable.
- p. 3-1, third para. "Galbraith, 2003" should be GES, 2003.
- **p. 3-4, Table 3-3.** Why are wood duck and hooded merganser not included in this list or receptors? We already have data that characterizes their exposure and MSU has already gathered eggs of both species.
- **p. 3-5, Section 3-4.** Can we infer from this section that if unacceptable risks are shown to apply to reproductive endpoints that this axiomatically implies risk to population sustainability (see general issue 5 above)?

- **Figure 3-1.** This conceptual model diagram of the terrestrial exposure pathways needs clarification: how are insectivorous mammals exposed via small mammals? Which of the species robin, house wren, and tree swallow is a carnivorous bird should the box be labeled Omnivorous/Insectivorous? How would piscivorous birds be exposed via a terrestrial food chain? Wouldn't birds such as robins or house wrens be depredated by carnivorous mammals?
- **p. 3-6, Section 3-6** identifies the "risk question" that should be the central issue of the proposed studies. However, as framed, this is not a question about risk at all, it is about impacts. The question should be: Does exposure to site-related COPECs result in unacceptable risks to ecological receptors?
- **p. 3-6, Section 3-6.** The Massachusetts Weight of Evidence Workgroup is referred to. If this reference is to be used a justification for the lines of evidence approach much more detail has to be given about the composition of this group, their regulatory status, the agencies involved, etc.
- **p. 3-6, Section 3-6.** How, exactly, will measurement endpoints be "evaluated" for the three listed attributes, particularly the second and third?
- **p. 3-6, last para.** The intent of this paragraph is not clear. What is measurement endpoint "outcome"; "indication of risk of harm"; measurement endpoint "weight"; "magnitude of response"? This seems to be an important statement of intent, but it suffers greatly from lack of transparency.
- **p. 3-7, first para.** What will happen in situations where multiple lines of evidence are not available? For example, if the only data for a particular bird species is egg residues (which may or may not exceed TRVs). Would the species be eliminated from further analyses or would risk decisions be made on the basis of the one line of evidence available?
- **p. 5-2.** If FAVs are to be applied to soils, sediments, diet, etc., they may also have to be used to calibrate the results of TRV data. If this is not done, the comparison of dose with TRV may be inappropriate.
- **p. 5-3, final para.** It is stated that the results obtained from the MSU sampling grids will be extrapolated to the wider environment of the site. However, since the sample sites that were chosen for the grids were subjectively selected (i.e. they were not, apparently, based on a random model or a systematic grid with randomized start point) any statistical inferences from a grid should be confined to that grid, or perhaps, to comparisons between grids. How will the risk assessors address this limitation?
- **Table 5-1.** The sample size for many matrices is given as 14. How is this arrived at given that there are only 6 grids and two sampling events per grid?
- **p. 5-5. Section 5.2.1.** Why explicitly is doubt being cast on the Saginaw Bay carp mink feeding study in a work plan? Is it being contended that the study has no predictive value elsewhere? Or is that the TCDD-EQ approach to evaluating risk is being questioned?

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- **p. 6-1, Section 6.1.1.** There is an inconsistency in the logic and terminology in the 2nd complete paragraph. If it is to be assumed that HQ values less than unity indicate that *unacceptable risks* are unlikely, then it should be assumed if the HQ values are greater than unity that *unacceptable risks* are likely. Also, what can be deduced if the HQ value is exactly one?
- **p. 6-1, first bullet**. See my previous comment on "potential risk". If the dose exceeds the LOAEL and the LOAEL-based HQ is >1.0 it provides evidence of risk not "potential" risk.
- **p. 6-2, bullet.** This is not completely correct. If the dose exceeds the NOAEL, but is less than the LOAEL, the risk manager must be included in the assessment of whether or not that level of risk is acceptable.
- **p. 6-2, Uncertainty approaches**. Will the uncertainty evaluation include those uncertainties that could shift the risk estimates upward, or will it be confined to those that might reduce risk estimates?
- QUAPP, p. 2-5. Is the identification of clean-up criteria a goal of the BERA?

QUAPP, p. 3-9. Typo in Table #.

Study Plans. Exposure Pathway Analysis (p. C-4). The stated rationale for this study largely ignores the results of previous studies. We know that various species of predatory and forage fish have bioaccumulated PCDD/PCDFs. We know what their tissue residues are. We know that at least two species of duck have bioaccumulated PCDD/PCDFs, and that their eggs have high levels of contamination. Every ecosystem component that has been thus far investigated has proven to be contaminated to relatively high levels. It is disingenuous to describe the information that has been collected thus far as "limited".

p. D-13. Use of HSI models. HSI models can provide useful <u>approximate</u> measures of habitat quality. However, their results can be over-interpreted: comparisons of two scores of (e.g.,) 0.8 and 0.4 may be legitimate, but a comparison of 0.8 and 0.6 may not be. Also, the main problem with most existing HSI models is that they have not been tested or calibrated in the field. Without this they are highly conjectural and probably not suitable for use in ERA. How will the HSI models to be used in this BERA be field-validated?

4.0 REFERENCES

ENTRIX. 2005a. Draft Baseline Ecological Risk Assessment Work Plan for Polychlorinated Dibenzo-p-dioxins (PCDDs) and Dibenzofurans (PCDFs) in the Tittabawassee River and Associated Floodplains. Entrix, Inc. East Lansing, Michigan. Prepared for Dow Chemical Company.

ENTRIX. 2005b. Draft Screening-Level Ecological Risk Assessment Work Plan for the Tittabawassee River and Associated Floodplains. Entrix, Inc. East Lansing, Michigan. Prepared for Dow Chemical Company.

GES. 2003. Tittabawassee River Aquatic Ecological Risk Assessment. Prepared by Galbraith Environmental Sciences, Newfane, VT., for MDEQ, Bay City, MI.

GES. 2004. Tittabawassee River Floodplain Screening-level Ecological Risk Assessment. Prepared by Galbraith Environmental Sciences, Newfane, VT., for MDEQ, Bay City, MI.

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COMMENTS

Draft Screening Ecological Risk Assessment Work Plan Tittabawassee River and Associated Floodplains, July 2005

The Dow Chemical Company Midland, Michigan MID 000 724 724

The following comments are provided to assist the Michigan DEQ in their review and refinement of the above draft Screening Ecological Risk Assessment Work Plan.

- 1. This workplan needs to be revised to incorporate MDEQ goals and requirements. Specifically, a risk management goal needs to be developed by MDEQ which states what level of resource protection is expected for water (e.g., refer to beneficial uses in Michigan water quality standards), sediment and soil.
- 2. Information needs to be provided on how threatened and endangered species will be addressed in the risk assessment. Consultation with U.S. Fish and Wildlife Service is required and needs to be supported with written documentation.
- 3. The MDEQ needs to establish the default list of screening level ecological benchmarks (Section 3.2.1) and the corresponding criteria to develop benchmarks when none exists. A chronic no-adverse-effect-level (NOAEL) for the most sensitive species (likely to be present) is recommended for the ecological benchmark. The USEPA Region 5 RCRA Ecological Screening Levels (to be updated August 2005) should be considered for the default benchmarks.

For <u>soils</u>, the Eco-SSLs and their methodology need to be followed. For <u>water</u>, the Michigan water quality standards needs to be followed. For <u>sediment</u>, the AConsensus based threshold effect concentrations (TEC) (MacDonald et. al. 2000, Arch Environ Contam Toxicol 39:20-31, Table 2) needs to be used to protect benthic fauna. The development of sediment benchmarks needs to follow the AProcedure for the derivation of equilibrium partitioning sediment benchmarks (ESBs) for the protection of benthic organisms@ (EPA-600-R-02-009, ...-010, ... -011, ... -012, and ... -013). Since the above sediment benchmarks do not consider the potential for bioaccumulation and trophic transfer to other aquatic life or wildlife, persistent bioaccumulative chemicals need to be retained for the baseline ERA. The Michigan DEQ needs to establish a list of bioaccumulative chemicals. The EPA report (EPA/823/R-00-001) by Michael Kravitz (see Table 4-2) can be used to create a list of bioaccumulative chemicals. This report is available at (http://www.epa.gov/ost/cs/biotesting/bioaccum.pdf).

Please note that some of the ecological benchmarks listed in section 3.2.1 do not represent current benchmarks (e.g., EPA 1999 National Recommended Water Quality Criteria and EPA 1996 ECO Update - Ecotox Thresholds).

4. The screening level data quality objectives in Section 2.1 needs to add chemical detection

limits, which corresponds with the screening level ecological benchmarks. This will ensure usable data Ato support the ERA@ (as identified in the SLERA Workplan Appendix A, 3rd sentence of the Introduction, Section 1.0).

- 5. This workplan prematurely presents steps associated with the baseline ERA (i.e., analysis and risk characterization) and these steps need to be removed from the Screening ERA. These steps are not supported in the decision tree (Figure 4.1).
- 6. The screening ERA will evaluate <u>maximum concentrations</u> in the environmental media (water, sediment and soil). The reference to Amaximum exposures@ in Section 4.1 needs to be revised. Likewise, in section 4.1, third paragraph the 2nd and 4th choices for selecting COPECs needs to be deleted as these are distinct steps for the Baseline ERA. The 3rd choice (background comparison) needs to be moved to the uncertainty discussion in section 4.2.
- 7. Figure 4-1 Decision Tree for Screening COPEC=s
 - a. When the AMDL is greater than the benchmark@ gets a AYes@ response, the route needs to go to ARetain COPEC@ as discussed in workplan. The A<u>collect additional data@</u> option, if applied, needs to route the process back to the initial decision step.
 - b. The term ACOPEC_{ref}@ is not defined or discussed in the report. It=s not clear if this is intended to be naturally occurring background levels of inorganic metals.
- 8. Since the screening ERA uses default exposure and bioavailability assumptions, discussion of these topics needs to be removed from section 4.2 and presented in the baseline ERA.
- 9. In Section 4.3, Scientific Management Decision Point #1, a fourth option needs to be considered: AThere is enough information to conclude that ecological risks are high enough to implement an interim measure or site cleanup activity.@

MEMORANDUM

TO: Greg Rudloff

FROM: Daniel Mazur and Greg Czajkowski

SUBJECT: Dow Chemical - Draft Baseline Ecological Risk Assessment Work Plan

Tittabawassee River and Associated Floodplains, July 2005

The following comments are provided to assist the Michigan DEQ in their review and refinement of the above draft Baseline Ecological Risk Assessment Work Plan.

- 1. This work plan needs to be revised to incorporate MDEQ goals and requirements into Sections 1.1 (Purpose and Scope) and 3.1 (Introduction for Problem Formulation). Specifically, a risk management goal needs to be developed by MDEQ which states what level of resource protection is expected for water (e.g., refer to beneficial uses in Michigan water quality standards), sediment and soil. The risk management goals and needed risk assessment products set the stage for the risk assessment with respect to what type of information is needed to support the risk management decision. This direction at the beginning of the risk assessment will keep the project focused on producing useful information for the risk managers.
- 2. In Section 2.2 (Scientific Management Decision Point #1) three potential decisions that can be reached following the SLERA are presented. Although these options are consistent with the 1997 U.S. EPA Superfund Ecological Risk Assessment Guidance, there may be an instance when screening values are exceeded by such a large degree (i.e., severe risk) that some form of cleanup or interim control measure would be appropriate (note, this could become one of the risk management goals for comment #1). A fourth decision option needs to be added to show that action (cleanup or interim measure) is required when severe risk conditions exist.
- 3. The selection of receptors of concern in Table 3-3 (Proposed Receptors) needs to follow after the conceptual model and assessment endpoints are established. Since no carnivorous mammal is listed in Table 3-3 (the short-tailed shrew is an insectivore) either the long-tailed weasel or a red fox would be preferred over a coyote (see Figure 3-1) as their feeding home range is smaller and would have greater potential exposure to site contaminants. Of the three mammalian carnivores the long-tailed weasel would have the smallest home range.
- 4. Sediment/ silt deposition on flood plain vegetation needs to be presented in the conceptual model (Section 3.5) for herbivore exposure. This exposure path way needs to be considered since previous studies have shown other herbivores (e.g., deer) to have high contaminant levels in their tissue. Please note the terrestrial vegetative sampling and analysis plan presented in Appendix C (Section 1.5.3, 3rd paragraph, first and last sentences) is designed to wash all

vegetation prior to analysis. This washing of vegetation is not recommended since it will remove any natural dust and river silt deposited on vegetative surfaces and will limit the risk assessment only to consider contaminant transport to plants from soil via root and vascular tissue systems.

- 5. Dietary exposure modeling (Section 5.1.1) does not indicate what is an acceptable exposure time interval for the representative species and the desired assessment endpoints. These exposure time intervals need to be identified and later compared to actual data collected along with variations from the acceptable exposure time interval discussed in the uncertainty section.
- 6. The reference (Travis and Hattemer-Frey 1991) cited in Section 5.1.1.1 (Exposure Characteristics of Avain and Mammalian Wildlife Receptors) for water ingestion, inhalation and dermal is intended for Human exposure not wildlife. This reference needs to be replaced with that given in the U.S. EPA Guidance for Developing Ecological Soil Screening Levels, OSWER Directive 9285.7-55 (Attachment 1-3, Review of Dermal, and Inhalation Exposure Pathway for Wildlife).
- 7. When a toxicity reference value (TRV) is developed numerous factors that may influence toxicity (e.g., retention time, absorption, detoxification, etc.) are not specifically measured. In selecting a TRV, factors influencing toxicity are assumed to be comparable when the TRV test organism is the same or closely related to the target organism. By inserting an adjustment only for "fractional absorption value" (FAV) in Equation 5.1 the exposure estimate will likely under compensate (when the test and target species are the same or similar) and will not consider other toxicity influencing factors. The FAV needs to be deleted from equation 5-1 and use the original exposure model developed by Sample and Suter (1994). Also the site use factor (SUF) appears to be incorrectly presented (see equation 7 in section 2.3 of the Sample and Suter 1994 reference) and should be expressed as "site area/foraging area."
- 8. Uncertainty (Section 5.1.4) in the tissue residue-based approach will be influenced primarily by the amount of time spent feeding in the contaminated area by a receptor. This sentence needs to be revised.
- 9. It's not clear how other modifying factors (Section 5.2.1.3.4) will be selected. Additional discussion is needed.